Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT
Benefits and Risks

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Amy Gutmann:
Ladies and gentlemen, we're about to start. If you would all take your seats, please. Welcome back for those of you who were here this morning, and those of you who are new, welcome to what has been to this time at least — and I'm sure will continue to be a very interesting and engaging set of discussions.

In his letter to the Commission, President Obama asked us to consider this research's potential benefits, medical, environmental, security and others, as well as any potential health, security or other risks. This, our third panel today, will address these issues, including whether synthetic biology offers unique potential benefits distinct from those that come from other types of science and technology and whether this technology might be applied to potentially dangerous ends. Our first speaker Dr. Allison Snow is a Professor of Evolution, Ecology and Organismal Biology at Ohio State University. Dr. Snow is a Fellow of the American Association for the Advancement of Science, a past President of the Botanical Society of America, and a former officer of the International Society for Biosafety Research. She was recognized by Scientific American as one of the top 50 researchers in science and technology.

Welcome, Dr. Snow.

Allison Snow:
Thank you very much. It's great to be here. Do I need to start the timer?

Amy Gutmann:
Yes.

Allison Snow:
Thank you. I'm really pleased to have a chance to talk to the commission and the other speakers here today. And I'm going to offer you a very different perspective I think definitely from what we heard this morning.

So, I think we all are learning as we go here. And I will give you sort of an ecological perspective.

As a background, I'm a plant ecologist. I study gene-flow through pollen and seeds. I study hybridization between related species, and I also work on assessing ecological risks of transgenic crops, especially those that can hybridize with wild relatives. I have about 20 years of experience on working on these types of biosafety issues related to transgenic crops.

As an ecologist, I'm also interested in understanding ecological effects of all genetically engineered organisms, which I will refer to as GEOs, including synthetic and partially synthetic organisms.

I was the lead author of a 2005 position paper of the Ecological Society of America. Some of the details of what I'll be talking about are fleshed out more in that paper. To set the stage for my comments, I'd like to talk first just for a few minutes about what ecologists do.

Just to give you a brief overlook about professional ecologists, we are professors, graduate students, wildlife biologists, natural resource managers, and other researchers, who investigate interactions between organisms and their environment. And so I mainly am thinking as my title slide suggests about the environmental releases of new organisms.

Our field is very interdisciplinary. We study all types of organisms from microbes to plants and animals and all types of habitats all over the world. We often focus on one level of organization, such as populations, communities, and ecosystems. And we look at many interrelated processes such as competition, predation, mutualism, the cycling of carbon, nutrients, and energy in the environment. And some ecologists like me study rapid and ongoing evolutionary change.

Much of the research that ecologists undertake relates to practical questions in agriculture and forestry, aqua-culture, and even urban planning. A common myth about the natural world is the idea there's a balance of nature, but nature as many of you know is not in a state of equilibrium. It's in a constant state of flux. And also organisms are not perfectly adapted to their environment. This means that in some cases, new traits ' such as those that synthetic organisms might have ' could allow a species to be much more successful than it was previously.

Ecologists are very familiar with the need for more sustainable approaches to growing food and fiber and creating biofuels. And we hope new approaches to these global problems can be attained using the tools of synthetic biology.

Now I'd like to focus on some possible environmental risks of releasing synthetic or partially synthetic organisms into the environment, whether this is intentional or not. So far, there's been very little public discussion of environmental risks. I was glad Dr. Venter brought this up this morning.

But usually, the environmental release questions are eclipsed by concerns about biosecurity and also by heavy emphasis on the benefits, potential benefits of synthetic biology. I think that in order to evaluate environmental risks, we really need specific examples. And we don't really have a lot of those yet.

We heard this morning that some of the applications aren't ready yet. So that makes it difficult to look at specific examples. As with previous GEOs, there's going to be a great deal of variation among different applications and their potential for harm and their potential benefits. And this is going to require a case by case approach. I don't think we can say all synthetic organisms are safe or all of them are dangerous. So far, most applications seem to be in the very early R&D stage. Those that are farthest along may involve completely contained synthetic organisms. And those should be less worrisome to ecologists than environmental releases--although leakage outside of contained facilities might occur and we need to know whether this would ever be a problem, especially when this is done at a very large scale.

For applications that involve bacteria, we heard about microbes this morning, I think it's important to remember that a bacterial cell is a self-replicating organism and sometimes when it's just referred to as a cell or a machine or a chassis, lay people might get the idea that this is not going to go out and reproduce in the world. But let's keep in mind that a bacterium is an organism.

Applications that are mentioned most often for field releases involve microbes and algae such as algae grown in acres and acres of outdoor ponds for biofuel. I'll say a little bit more about this later because this is one of thefew clear examples that is going forward quickly is engineered algae.

Unfortunately, it's hard for the public or public researchers to know exactly what's under development. And this is partly because we're early in the stage, but also because a lot of this information is proprietary. And the parts that are moving quickest are being moved forward by an industry and that is not public information.

For example, ExxonMobil is spending hundreds of millions of dollars to develop genetically engineered algae with Synthetic Genomics, the company that Craig Venter has founded. But we don't know details yet. I dug around before this meeting to try to find out more about what they were doing. I couldn't get any information. It would be useful to know what type of algae they are working on, whether they will have suicide genes if they are going to be grown in open ponds or maybe they are going to be in bioreactors. Will they be in freshwater or saltwater? All of these kinds of questions would be helpful if we had answers to those.

So as a general framework for evaluating risks, I'd like to say a little bit about what I see as different with synthetic biology compared to what came before. And as many of you know, there's no clear distinction between traditional genetic engineering and synthetic biology. We were given a notebook with a lot of different definitions.

People have been making synthetic genes for years, so that's not new. But both can involve the transfer of genes that confer new traits into a recipient organism. It could be one or several genes, artemisinin in this case, or a whole genome sometime in the future. So, right now, we're at that intermediate stage, I think, where it's one or two or several genes going into the new organism. And I view synthetic biology as a very advanced type of genetic engineering. A recent article in Scientific American called it "genetic engineering on steroids." Maybe that's a good analogy.

Regardless of which new GEOs are proposed for outdoor settings, I'd like to review briefly four general guidelines that ecologists would offer of what should be considered. And these are discussed in more detail in some of the reports that you have been given.

The first guideline is that we do need to be very careful whenever self-replicating organisms are released in the environment, especially if it's an intentional release but also for unintentional releases. Many of them will do no harm whatsoever. But important exceptions could occur, especially if the genetically engineered organism can multiply and become more abundant out in the environment.

Just as a hypothetical worst case scenario: maybe we might someday have blue green algae that are engineered for biofuels and they have to be very hearty to survive in outdoor ponds. So they have been engineered to be hearty, high-yielding, blue-green algae grown on thousands of acres. And they might spread to natural habitats and might spread to lakes or rivers or streams where they could start flourishing. And they may be better than the algae that are already there. And I'll go into this in a little more detail. But they could have the potential to displace other species and create algae blooms known to cause suffocation of fish and other aquatic life. Some types of algae actually release toxins into the environment. So this would be a bad decision to go ahead with this kind of application. It's just a worst case hypothetical scenario, but it gives you an example of what we want to avoid. In some cases, a GEO might spread to new climate zones or new habitats like other invasive species.

A second general principle is that novel GEOs that seem innocuous or weak, or they even have suicide genes, might evolve to become more successful once they start reproducing out in the environment. Even if they are highly domesticated, mutations and other unexpected properties might allow them to survive in certain environments.

Physical containment or biological containment, which is sometimes given by suicidal genes or chemical dependencies, may not work forever or in all cases because mutations and human error and unexpected events might allow them to escape. And it would only take a few to escape in order to propagate. So if they really were hearty, these techniques may not be successful at containing them. Also, the potential for rapid evolutionary change is especially high in microbes. And some will die out, but others could thrive and evolve, especially GEOs that could exchange genes with other lineages or other species could create hybrid progeny in which the most successful new synthetic genes would be promulgated in their descendents. We can't necessarily assume that all domesticated or supposedly suicidal GEO organisms are not going to be able to persist in the environment.

A third guideline is that once these organisms are released, they cannot be taken back. So this is a really big difference between a chemical spill or pollution where it might be able to be cleaned up or degraded. It's just obvious fact that organisms that reproduce have the potential to be out in the environment forever. There's no way to find and kill every last one, especially in the case of microbes, but also for plant and animal species. We have never been able to — very rarely in the whole history of trying to get rid of an invasive species — have we been successful. So, the dispersal of some GEOs could be rapid and widespread and we have seen that with other species as with globalization and traffic around the world. It's very easy for organisms to spread.

A fourth general guideline is that predicting which new organisms might cause irreversible harm is extremely challenging. This is much easier with a genetically engineered crop like corn or soybean because those are domesticated. We have a lot of familiarity with them. They are completely dependent on humans and they don't have any wild relatives, at least in the United States. So with some of our earlier experience with crops, it's been easier to have a baseline for comparison and to look at the new characteristics and say we don't think this is going to cause problems in the environment.

However, we don't have much experience with cultivating micro-algae or bacteria outdoors, let alone new life forms that might be entirely synthetic. New types of really different bacteria? No experience. This brings up the question of whether regulatory agencies will be able to monitor and evaluate new types of synthetic or partially synthetic organisms that are proposed for release. And I'm glad that Michael Rodemeyer will be addressing this tomorrow. It's a question that has come up a couple of times this morning and it's a big one.

In summary, the challenges in approving novel genetically engineered organisms for environmental release are likely to become much, much larger in the next five to 10 years. And so this is something for you to think about.

To begin to tackle some of these issues, I think the general public and public researchers need more information as soon as the first applications are being developed — which is now. They are really being developed now.

And bioethics decisions that you all will be thinking about, you really need accurate and realistic information about how the technology will be used. It's like any technology. It could be used for good or bad. And you need more information about that.

Which species will be developed under what conditions for outdoor releases? What are some possible risks? And what are some possible unintended consequences? Before regulatory agencies decide on whether an application should move forward, assuming they can be regulated, we need analyses of ecological risks and benefits.

And these ecological analyses should not just come from the industry that's developing them, but they should be independent. Ideally, they would be published in peer-reviewed journals or other types of reports that would be available to the public such as National Academy of Science report.

For example, a good start for micro algae would be to publish professional monographs dealing with the biology and ecology of each species and its close relatives including information about how they reproduce, how they spread, whether they exchange genes with other strains, whether they have been bred to be suicidal, whether they could become more abundant or might die out, and whether they produce any kinds of toxins or other side effects.

Ecologists can help with the development of synthetic GEOs that will minimize risks and ecologists will want to get involved as that moves forward. For example, the choice of organisms and the traits should be discussed in light of possible ecological risks, outdoor risks that many engineers and molecular biologists don't normally think about. You need to have many people thinking about these issues. And key knowledge gaps can be addressed with research.

But ecological research takes time and funding. This is why risk assessment research shouldn't be left for the last minute. It should go in tandem as the development of these products is moving forward. When more is known about specific applications and possible risks, it would be great to have a lot more open debate and discussion. This is necessary to avoid bad decisions and allow safe uses to go forward.

I think there is a good precedent to that, even with non-transgenic biofuel crops. There's a lot of debate about which crops should be used and under what conditions. There are a lot of publications out there about that. It would be nice to have another layer that would include these new organisms.

So, in closing, I'd like to read a quote from an editorial about synthetic biology in Nature magazine that maybe most of you saw. It's from May 27th, 2010. And the title is "Challenges of Our Own Making." The editors say and they mention this committee. And they say that "Where there are concerns, they now need to be developed beyond the knee-jerk sound-byte." And I couldn't agree more.

We have had to use a lot of sound bytes in our short presentations. But I really look forward to a lot of deeper discussions and debates on these issues.

Thank you very much.

Amy Guttman:
Thank you very much, Allison. And what you call soundbytes, I think, is way more subtle and sophisticated.

Allison Snow:
I didn't think so.

Amy Gutmann:
And highly informational than what goes for soundbytes in the world out there.

Allison Snow:
Okay.

Amy Gutmann:
So, thank you very, very much. Next is Jim Thomas. Jim Thomas is the Programme Manager with the ETC Group. It is a Canadian-based international civil society organization that analyzes the impact of new technologies on society. Mr. Thomas is a prominent critic of synthetic biology and has gone on record opposing voluntary governance strategies for the field. And I'm sure we'll hear some more on this. He is importantly the author of "Extreme Genetic Engineering: An Introduction to Synthetic Biology." Mr. Thomas, we look very much forward to your remarks. Thank you for being with us.

Jim Thomas:
Thank you very much, and thanks to the commission for inviting me to this more than and very important meeting. I am encouraged that President Obama is choosing to examine synthetic biology. I hope this really opens up a debate that will allow for the proper regulations and oversight of this technology.

I speak for the ETC Group. We are a technology watch-dog organization that has been looking at synthetic biology for about five years now. And our mandate is to work with global civil societies — so environmental groups, indigenous groups, and farmers' movements — to understand how this technology impacts the disadvantaged and the dispossessed who, in fact, make up most of the world's population. I do very much hope there will be an opportunity later in your process to hear from such communities directly about how synthetic biology is going to impact their livelihoods, their territories, and their rights.

I'd very much echo and support some of the concerns you have heard from Professor Snow about the environmental releases of synthetic organisms. You may be aware that the U.N. Convention on Biological Diversity has a sensible proposal in front of it for a moratorium on environmental releases of synthetic organisms. And, in fact, similar process to this last year by the European Commission Ethics Group also highlighted the need for long-term ecological studies before environmental releases can be countenanced.

Our view is that synthetic organisms should be locked up in the research lab — and that's different from the commercial biorefinery which is potentially very leaky and experimental. But I'd like to mostly talk about — what I'd like most to talk about boils down to one phrase. To remind myself I have actually put it on a button: "It's the bioeconomy, stupid." And that's a message to me to remember that — although I have extra buttons if you'd like some….

In fact, I was tempted to write "It's the Stupid Bioeconomy." That might have been more appropriate. And the point is this: any meaningful assessment of synthetic biology as a technology has to grapple with the socioeconomic impacts of the industry that it gives rise to. And if this new platform of engineering cells in the factories in order to make chemicals and fuels and plastics really work. One might think it won't work, but, if it does, it's going to have a radically different model of production that we're going to see that's being variously called the bioeconomy and bio-based economy.

Having watched this field for about five years, I am convinced that what matters about synthetic biology is the emergence of the bioeconomy that it creates. I f you don't look at the broader economic shifts that are at play, you're going to miss the real socioeconomic impact of synthetic biology. The bioeconomy will reshape the world and impact rights and potentially fuel inequalities.

To give you a sense of what I mean by this, about how technology can really shift an economy, I want to suggest an historical thought experiment. Let's imagine that it's 1828 and this commission is being brought together not to look at the synthesis of a genome but synthesis of urea by Frederick Voller, the Voller synthesis rather than the Venter synthesis. And you've been asked to look at the implications of the emerging field of synthetic chemistry instead of synthetic biology. Playing that historical game turns out to be tremendously illuminating. Although history doesn't repeat itself, as Mark Twain says, "it sure does rhyme." And questions that early 19th Century critics' contemporaries asked about synthetic chemistry are very similar. They asked, "Are synthetic chemists playing God? Will they make weapons of mass destruction? And will patents on synthetic chemistry lead to overbearing monopolies?"

Well, the last two questions resolved themselves very clearly in the following century. We saw synthetic chemical weapons released in the trenches of the First World War, in the gas chambers in Auschwitz, over Vietnam, and we saw a very powerful monopoly emerge in the case of IG Farben, really a poster child of monopoly, and we still have a very concentrated chemical industry.

And I think what's most interesting with 100 years of hindsight are the questions that were not asked, questions like: What would synthetic chemicals mean for human health and the environment? That question didn't get an airing until 1962 with Rachel Carson's "Silent Spring." And even when she did bring up these questions, she was vilified and attacked as an emotional and unscientific woman, as being an alarmist — just as cautionary voices on biotech are attacked today. Truth is: she wasn't alarmist enough. If you look at the situation, the communities of color in Louisiana's "cancer alley" or women who are feeding synthetic chemicals in their breast milk to children daily, or the fact that we live under a hole in the sky created by synthetic chemicals. Those sorts of situations would be been hypothetical and far fetched in 1828, but history changes that.

Imagine you told an 1828 ethics commission about the litany of wars and human rights abuses and environmental destruction that came, not so much from the products of synthetic chemistry, but from the quest to secure the feedstocks to maintain the industry that came from synthetic chemistry and from oil spills in the Gulf of Mexico to oil wars in the gulf of Persia to the engulfing climate crisis. The industries that came out of synthetic chemistry have not only transformed fossil fuels into plastics and explosives and so forth, but they have transformed our global economy even transformed the atmosphere.

And today's synthetic biology industry now says they are going to get away from all that. Dr. Venter, even as he is making deals with BP and Exxon, hopes to put the petro-chemical industry out of work proposing a biotech- enabled transition to an economy in which living plant material rather than fossil plant material is the key feedstock of production. This is the bioeconomy, the bio-based economy, we hear so much about. And it's the reason that synthetic biology is attracting so much money from Fortune 500 companies, like flies around fermenting biomass.

What matters to them is that synthetic biology might make this bioeconomy possible. And so gene giants and forest barons and agro biz companies hope to control biomass feedstocks in the new bio-economy.

It's the bioeconomy, stupid. That's what matters.

And I think in the process, it might become like the petro-economy. Trying to guarantee the supply of sugar or cellulose or algae for the vats of synthetic organisms pumping out product will require a massive reorganization of natural resources, a grabbing of land and stripping away of plant matter and water and nutrients that could affect every part of the planet and some of the lives of the poorest people on the planet. I think we can already begin to see this underway.

I want to consider three snapshots of the synbio-enabled bioeconomy as it is already emerging.

We have heard about Amyris Biotechnologies that, next year, will produce a hydrocarbon fuel derived from cane sugar with synthetic yeast in Brazil. And the taking of sugar for vats and other biorefineries is increasing the sugar-growing region destroying the very fragile Serato region, second only to the Amazon in terms of biological importance in Brazil.

The sugar, itself, is cut down by Brazil's army of landless migrant workers, many of whom are in slave conditions, who undertake back-breaking slash-and-burn cutting, which puts many of them out of work by the time they are 25. It simply wears them out. And the burning of the sugar cane, which is part of the process, releases large amounts of toxins, a large amount of greenhouse gases making Brazil the fourth largest emitter of greenhouse gases in the world.

Amyris claims this is a "no compromise" green biofuel. However, I rather suspect the sugar slaves and those whose rights and territories have been compromised would disagree. In a way, they are already being affected by the bioeconomy.

A second snapshot: we have heard about the work by Amyris to produce the artemisinin in a vat. While producing artmisinic acid is a laudable public health goal, this method of production is not necessarily the most just approach. It looks set to undercut the price of natural artemisinin grown by thousands of small farmers in East Africa and Southeast Asia. Its threat to the livelihood of farmers is the fact that artemisinin might be produced synthetically in vats. Once again, history is rhyming.

Back to the history of synthetic chemistry: The first commercial products, which were synthetic dyes, put out of business large numbers of indigo farmers in India and Bangladesh who were unemployed, and there was mass starvation in a short period of time. I'm not saying the artemisinic farmers of East Africa will necessarily suffer this fate, but there will be massive economic dislocations as we begin making our commodities of our vats of synthetic microbes out on the fields where people actually work.

Jay Keasling of Amyris is fond of saying synthetic biology means that anything that comes from a plant can now be grown in a vat. Well, many of the poorest people in communities in the world depend on selling plant-grown commodities and just the prospect of replacing those commodities with synthetically grown commodities is going to worsen the economic situation of the world's most vulnerable people.

A third snapshot of the economy, the new bioeconomy. I'll go back to the question of algae. In Dr. Venter's algae project with Exxon, he talks about turning sunlight and carbon dioxide into hydrocarbon fuels. There's much more at play.

You also require large amounts of water, nutrients, and, most importantly, land. And in a time of water crisis, we're going to see additional amounts of water being pumped probably to deserts, rather than to agriculture. We're going to see nitrogen and phosphate-based fertilizers added at quantities higher than currently added to crops because there's no soil in these systems. And the fertilizer production is not only energy-intensive but, in the case of phosphate fertilizers, it's currently peaking. The reserves are in decline. What phosphates we're now mining need to be prioritized for agriculture. We're looking at a food-versus-fuel dilemma of the sort that is still pushing people into hunger around the world.

And the land required is not insignificant. Dr. Venter told Congress he was looking at facilities about the size of San Francisco. In fact, MacArthur Genius Fellow Saul Griffith has calculated if you come up with a synthetic algae four times more efficient than current algae, you'll require one Olympic-sized swimming pool full of algae every second for the next 25 years in order to reach just half a terawatt of energy. That's like putting slime over all over Texas and Arizona. And that's just half a terawatt of energy. The world uses somewhere between 12 and 16 terawatts, most from oil, coal, gas.

All this points to an underlying fallacy with the idea of the bioeconomy: the assumption that somehow there's enough biomass, water, nutrients, and so forth to sustainably transition to using living feedstocks, and really there is not.

Human beingshave already appropriated about a quarter of biomass. And if you want a sobering reality on the bioeconomy, I ask you to look up the term "earth overshoot." Earth overshoot refers to the way in which societies are already going beyond the carrying capacity of the planet in terms of appropriate biomass, water, and other ecosystems resources. And every year, the rate at which we're overshooting that capacity gets earlier and earlier. Last year, it hit on the 25th of September — and there have been over 25 years of this. So that's not in any way a renewable economy. It's potentially a very stupid economy.

What's not stupid is to be able to act with foresight, intelligence, and humanity. And that's what this commission has the historic opportunity to do now. The fact is, there was no commission of inquiry into synthetic chemistry in 1828. John Quincy Adams was not Barack Obama. And there weren't professional ecologists to organize civil society organizations able to think through the implications and offer cautionary voices about the terrain ahead.

President Obama has offered you this tremendous opportunity to learn from history, rather than to be doomed to repeat it, rather than for it to rhyme. And you get to ask the important questions now, and not centuries too late.

I really encourage you to be brave, thoughtful, and far-sighted in your analysis. And the ETC Group and other civil society groups will be inputting into this process and are very much ready to help in understanding what synthetic biology and the bioeconomy it creates means for our common future.

Thank you very much.

Amy Gutmann:
Thank you, Jim, very much. You have given us a lot to think about and to deliberate down the road.

Nancy King, our third speaker on this panel is a Professor of Social Sciences and Health Policy in Wake Forest University School of Medicine and is Director of the University Center for Bioethics, Health and Society. Her scholarship addresses a wide range of issues in bioethics. Professor King was also a member of the NIH Recombinant DNA Advisory Committee. We are very happy that you can join us today.

Nancy King:
Good afternoon, everyone. I'm honored and humbled to be able to attend this first meeting of the Presidential Commission and to be included among this company of scholars.

My contribution to this discussion is almost seems to me like a recap of things we have already heard today. A reminder of things we already know, a lot of which have already been discussed and have definitely been addressed in much of the literature as you saw in our briefing books that have been mentioned. All of these are things we need to keep in mind as synthetic biology and related biotechnologies continue rapid investment. I'll make a few basic observations.

Number (1) Risk and benefit are not parallel terms. We should always talk instead about assessing and balancing risks of harm and potential benefit. I'm actually glad to hear that President Obama was careful in his use of language, but many of us aren't. It's especially important in the research context to use terms carefully when experimental interventions have not been proven safe or effective. Now, if brevity is essential, we should talk about benefits and harms, rather than risks and benefits. You can easily see why the longer terminology is preferable because it is a reminder that the harm-benefit analysis is complex and we need to examine all the benefits and harms rather than speaking loosely about them. We need to talk about their anticipated nature, magnitude, duration, and likelihood.

Why does it matter to be so clear and specific? Well, there are at least three reasons. It helps us avoid the misleading implication that benefits are certain and harms are unlikely. It helps promote a more nuanced understanding of potential benefits and risks from any intervention. And it ensures recognition of the trade-offs that exist in every medical and scientific advance.

Now, Observation (2) Assessment includes context. We have already talked some about the context specificity of synthetic biology, but assessing and balancing risks of harm and potential benefits is also always context specific. It really matters what you're developing and how it will be used. Obviously, the context includes consideration of the available alternatives — for example, a me-too drug should be evaluated differently from a drug to address an orphan disease with no effective treatment because the harms and benefits matter differently depending on how they fit into what's available. Often what's newest may be the most needed and least predictable. And as we have heard, synthetic biology presents many uncertainties and unknowns, but also novel pathways to potential benefit. And we also know from the history of other novel biotechnologies, that benefit may or may not materialize.

Context is individual and highly specific and case based, especially in a broad and variable field like synthetic biology. And we know there's always residual uncertainty in the application of science and its products, but assessing and balancing risks of harm and potential benefits in the research context is always different from doing so in the application of products that have come through the research trajectory.

Now, uncertainty is going to be greater earlier in development, but it may also increase when a product or intervention moves from research to post-approval uses. The long-term individual public health and environmental affects of the introduction of a new intervention should also be considered and we know this from many current examples such as studies of drug metabolites in the water supply and the cumulative effects of radiation from diagnostic imaging.

So, it's essential to acknowledge that some things are uncertain and some things are unknown about every novel biotechnology. This is a really, really obvious example. Nobody in this room would disagree. But it's still extremely important to say we have to consider the existence of uncertainties and unknowns always. What should we be thinking of is whether nothing really is new here. Some people have argued, including today, that current developments in synthetic biology are really only incremental advances beyond novel biotechnological developments generally. If that's the case, nothing much really is new, and harm-benefit assessment for synthetic biology is not going to be significantly different from that of other novel biotechnologies — including, for example, gene transfer and genetic engineering, tissue engineering, and regenerative medicine and nanotechnology.

So how well are we doing now in these assessments and in working to minimize the risks of harm? Well, oversight of all of these related novel biotechnologies is young and really still evolving. Even the Belmont Report acknowledges the difficulty of analyzing limited information to reach systematic, non-arbitrary conclusions when assessing potential benefits and risks of harm and research generally. And recent literature on harm-benefit assessment in research, as for example done by IRBs or in the scholarly literature discussing the meaning of minimal risk, recent literature shows that we're really still not good at doing this.

Now, synthetic biology may be the most complex and wide-ranging of novel biotechnologies, but it's really nonetheless only the latest illustration of empirical and conceptional challenges we haven't fully addressed. And these challenges appear more urgent each time something new comes along.

On the other hand, what if everything is new? Now, some people have argued, some folks today as well, that synthetic biology is different in kind from other new biotechnologies and probably more people say, well, it's not really different-in-kind, but it could be different enough in degree, either now or later, to become different-in-kind. And, the arguments made in support of significant difference either on the risk of harm side or potential benefit side includes some things that have already been mentioned, such as: the rapid development of cheaper technology that's easier to acquire and manipulate (thus, raising the possibility of basement biohacking) and the capacity to work on a far larger scale and to combine technologies (thus, greatly speeding progress and the potential for effects on both individuals and the environment). A lot of developments are already being seen in genomics, nanotechnologies, and regenerative medicine.

Maybe there is one truly novel factor in synthetic biology, which might be the argument that the engineering of increased difference is a safety measure. Now, a direct relationship between difference from existing interventions and potential benefits is, of course, the standard expectation in all novel technologies. But as far as I know, proposing that increased difference increases safety isn't an argument that is usually heard. So the attempt to ensure that biosynthetic organisms are very different from and therefore incompatible with the biosphere, unable to combine or compete with bio-organisms or survive independently, is an attempt to minimize risk of harm.

We know increasing difference also increases uncertainty and the success at the attempt itself as we heard from Dr. Snow is uncertain. So this possibility needs to be incorporated into harm-benefit assessment. I'm just not sure how to do that.

Another observation (3): Biosafety and biosecurity systems are leaky. Now, biosafety and containment systems and practices have advanced a great deal in recent years, but there's really still a long way to go. We have clearly demonstrated this in gene transfer research and nanotechnology research and production and especially since the post 9/11 increase in biodefense and emerging infections research. For instance, there's only a limited number of Biosafety Level 3 and Level 4 labs in the world to do work that requires that level of containment or we think requires that level of containment. And the number of trained personnel available to work in high containment facilities is limited as well, which is a problem that's complicated by biosecurity concerns.

Dual use concerns are ubiquitous and of long standing in many areas of research as we have heard from Dr. Venter, but we're really just beginning to develop good biosecurity measures to address them. Basically, in order to assess the risks of harm from intentional misuse, it's necessary to anticipate unintended risks of harm, and yet the relationship between biosafety and biosecurity is to some extent still under-examined — although both Dr. Venter and Dr. Church did better than most in connecting the two.

Moreover, restrictions on information-sharing among scientists can cut in a lot of different ways. For instance, it could impair efforts to minimize risks of harm — whether those restrictions result from the protection of proprietary information or from concerns about security. And coordinating and enabling effective monitoring and oversight of both biosafety and biosecurity measures (for example, through NSABB and institutional biosafety committees) also presents a real challenge.

A final observation (4): Because nothing is new and everything is new, we really need to rethink uncertainty. When assessing harms and benefits, how do we know what works? How do we know when we've actually gotten to something that is an improvement, that is beneficial? It's an especially relevant question when the anticipated benefits are unprecedented, whether those benefits arise from say, for example, re-growing limbs and organs through regenerative medicine and tissue regeneration or from synthetic biology. If you have never seen something before, you can't necessarily measure when it's effective.

Harm-benefit assessment is further complicated when a novel intervention moves from the research arena to being a product because then its scope of use widens, the population affected increases and diversifies. And thus its harms and benefits change. Part of the challenge of coming to terms with uncertainty lies in attempting to predict this expansion of effects. It's necessary to recognize the difference: uncertainty, risks of harm, and potential benefits all may increase together. And also, at times, obvious consequences may be overlooked. We have only to examine some of the best-known examples of risk materialization in gene transfer research to be reminded of this.

So, consider, for example, the well publicized deaths of research subjects as different as Jesse Gelsinger, or Jolie Moore, or the several young boys with x-linked severe combined immune deficiency who developed leukemia even as their genetic disease was significantly ameliorated, or the subjects in hemophilia trials who temporarily showed viral vectors in their semen even though their gene transfer injections were into their penises. Each of these much discussed and exhaustively researched instances of risk materialization reflect the complexities of science, the frailties of human understanding, and the difficulty of assessing and balancing risks of harm and potential benefits in very, very different contexts.

Synthetic biology appears to present a similar degree of uncertainty at least. A lot of provocative language is used to describe both its promise and its perils: unprecedented, revolutionary, dramatic, unique. The scientific and policy infrastructure that we really need to determine whether these terms truly apply I think really needs to be coordinated and strengthened.

So, two things that we may need to come to terms with in synthetic biology are some very long-term monitoring and continuous harm-benefit reassessment. This is something that we basically already know is needed from gene transfer, regenerative medicine and nanotechnology. And two things we need to work toward to address uncertainty in synthetic biology are an integrated system of oversight and collaborative harm-benefit assessment and discussion with regard to individual and environmental effects and also with regard to social effects and health equity. We also know this from biodefense and emerging infections research, from gene transfer, and from regenerative medicine. Fortunately, this commission is very well-positioned to move forward by fostering much-needed engagement with these questions for synthetic biology.

Thank you.

Q & A

Amy Gutmann:
Thank you very much, Nancy.

For those of you who weren't here this morning and those of you who were as well, I will just repeat it very quickly. We will be open now for questions from our commission members. And then I will open the floor to the public. And as is our tradition, I ask the vice chair if he would like to lead off with a question.

Jim Wagner:
I would. And, first of all, thank you all very, very much. Having read some of the positions, but hearing them expressed personally is especially helpful. I heard something that I want to bounce off of you. And that is that there may be categories within which we should approach differently this analysis and this benefit-harm analysis. I think I heard three categories. And I want you to comment if this is right.

And the first of those is the work that's done in research, in the research labs. Mr. Thomas, you think actually said some things belong sequestered in the research lab.

And the second category, the second and third categories actually make up what you call the bioeconomy. They would include the applications of synthetic biology in contained processes.

And third, would be to your point Ms. Snow, the intention to actually deploy GE Os as you refer to them.

It's three categories. Research, contained application, deployed, environmentally deployed application. Is that fair? Is that a fair categorization? Is that one way for the commission to imagine how it might explore addressing the different needs for benefit and harm?

Amy Gutmann:
Jim, why don't you weigh in?

Jim Thomas:
I think it's a very interesting categorization. It certainly speaks to the safety risks. And to some extent it speaks to the socioeconomic and justice risks but there's obviously a continuum between those three. You know, if research is being done to understand how organisms work, you know, we understand by building, we don't need to go beyond the research laboratory. It stops there.

But if it's being done in order to develop a product and you have a certain amount of financial and political investment behind that, then it's going to move on to whether it's contained use or deployment. Likewise, once you move into the commercial sphere, and I think that's a very key line. I think it's not just the line at the lab door. It's the line between research and commercial use that's significant.

I think maintaining commercial-environment containment, you know, is a nice fantasy. And it might work. But over the period of time, I think it's going to get lost. So I think we should think that any commercial use is going to end up being a kind of deployment because there will be unintentional escapes. So I would draw more useful line between research and commercial use.

Amy Gutmann:
Allison.

Allison Snow:
I think those categories are very helpful and perhaps your committee could think about do you have any concerns about basic research that is in synthetic biology. And that has been covered quite a bit more than these applications that are still very young. And the applications involve the bioreactors in the field. So if you feel that the basic research is appropriate and being done, you know, under the best intentions or however you would address that, that could be a separate category that you would look at from the others. So I think that's quite useful the way you have described it.

Amy Gutmann:
Yes, Dan.

Daniel Sulmasy:
I'd like to ask a little bit about the current status of environmental impact assessment because my understanding is the usual way it works is there are theoretical concerns and theoretical safeguards. And then we release it to the environment and then monitor as Nancy was saying. And then sort of hope for the best.

But I wonder whether things have evolved to an experimental basis for doing this, which is often very difficult in ecology, somewhere between isolation and release to the environment. So there could be a more rational basis for assessing whether certain modifications and organisms are in fact effective, if those genes are transferred from one organism, to another etc. What's the state of assessment?

Amy Gutmann:
Allison, we'll start with you.

Allison Snow:
My familiarity is with genetically engineered crops. And it is sort of hard to make a comparison with microbes and algae. But you start out with lab experiments and work towards small-scale field releases that require approvals from the Federal government and then sometimes there's a larger scale field release and then you're out. Basically, the regulatory agencies have a real tough job making those calls because they never have enough information. And I think you'll hear a lot more about that tomorrow. Meanwhile, ecologists and environmentalists are throwing out their opinions all the time and so are other people. And so there's a lot of debate and discussion. I think that the regulatory system has worked quite well in preventing terrible ideas from going forward. So all that discussion and those stages have been quite effective so far. I just don't know if we can keep up with the pace of change that's happening now and into the future.

Amy Gutmann:
Interesting. Nelson.

Nelson Michael:
This is probably more directed to Mr. Thomas. I travel to Kenya frequently. My program has a very large HIV/AIDS care and treatment program there as well as research activity in the western highlands. And that country, as you probably know, to use an example from there, is burdened greatly by diseases of poverty and diseases of pandemic nature. So if you look at Nairobi which is surrounded by a huge influx of very poor people in the Canberra slum, they have come there because they basically have been seduced away from subsistence farming, which worked, to come to the promise of working in a place like Nairobi where, of course, they have become a most at-risk population.

You described the potential hazards of synthetic organisms in terms of toxins, ecologic damage, and impact on most at risk populations. The current trajectory of what the state of the world is right now, these are all issues that are in play. And there's great suffering in that part of the world just because of the fact there isn't clean water. There aren't the provisions of inexpensive therapy. There's essentially no middle class. The subsistence farming has in some ways been influenced by the growth of cash crops that largely go outside the country like tea and flowers.

So what I'm trying to understand is what your current view would be on a tool like synthetic biology, and what would the constraints you would see to potentially use such a tool because things are bad the way they are now. If a tool has a promise of making things better — agreed there are lots of uncertainties — but how do you balance the views that you very articulately put with, I think, frankly, the real-world suffering, that occurs as you speak?

Jim Thomas:
I don't know the situation in Kenya, so I'm going to talk more generally. Obviously, the move away from rural livelihoods to being pushed to the cities happens all over the world. And it's definitely causing, you know, a number of problems. Your question says we have a deeply unjust situation in countries where people have been pushed off the land they have subsisted on for a number of reasons. Maybe we can use this tool to ameliorate their conditions.

I would suggest that if we would start with the problem and how we address the problem, we would be looking at things like land reform. We'd be looking at things that would allow people to return to land that's been taken from them. And when I look at where the bioeconomy is going, there are large amounts of land that are going to be required to grow biomass feedstocks, for example. That's just going to exacerbate those root causes.

So, yes, there's an interesting discussion to be had. Can we use these tools to ameliorate people's suffering, given that they have been pushed off of their lands? But shouldn't we be trying to prevent further dispossession of land? And it's not a small issue because the idea that the bioeconomy is going to find marginal lands where it can grow biomass that doesn't get used is entirely a fantasy.

Marginal lands are where people now live, having been pushed off of better lands. And the new bioeconomy is going to end up, in the first phase, consuming the old bioeconomy. People already use firewood and they use wild crops and so forth. And that's what's going to get displaced in the first instance. So unless that root cause is addressed in how this economy develops, then using the technology to throw life lines is just going to be chasing after the problem.

So, yes, there may be uses and vaccines here and so forth that are useful. But if you at the same time expand in an economy that is going to worsen the original problem, then I think that's counterproductive. I don't know if that answers your question.

Nelson Michael:
Define whether or not you believe this tool is incapable of ever being used for any purpose — or are your concerns just that we should take a measured approach to consider its possibilities since largely it's unknown?

Jim Thomas:
The question there is who are "we"? If you are talking about the use of synthetic biology to improve the situation in Kenya or Brazil, wherever, that discussion has to involve the people who are most impacted. It's not for "we" sitting around a table in Washington to determine the most appropriate use of the technology or whether the technology is the right place to start to address those problems. If we're going to have that discussion, those communities need to be here at the table. I don't feel that I can speak to that.

Amy Gutmann:
John.

John Arras:
Thanks again for another terrific panel. I wanted to address Jim Thomas with a question.

As a former Peace Corps volunteer, I appreciate your bringing the concerns of the global poor to the table here. But I'm still sort of puzzled about what your bottom line is. And in particular, I'm puzzled about exactly how that sort of a prohibitory policy will actually work. So toward that end, can you help us by naming historical analogies where technologies have been prohibited successfully for long periods of time?

And can you think of a — can you think of developments in any science where basic research has flourished and been supported by government and so forth without sort of leaking out into the economic domain as well?

Jim Thomas:
Technologies that have been taken and turned around and been prohibited: land mines come to mind. There are still land mines in existence but there's a process in place to try and remove them.

Yes, it's true. It's very hard to find examples of technologies and sciences that moved ahead without commercial and establishment support. History, you know — it's hard to see what didn't happen in history. And I think what this points to, though, particularly as technology and science becomes ever more important to the questions of development and questions of environmental sustainability, we need to have processes in place where we can have those discussions before it's too late. And that's — yeah, I agree. That's a new thing. I don't think we invented those procedures. I think there have been attempts.

The Swedish government had something called Siesta, which they developed 15 year ago which was an attempt to evaluate technologies as they were developed to see whether they were socially appropriate and should move ahead. Siesta got put to sleep. And some of the mechanisms, that would have done that at the international level, whether that's the UN Center on Transnationals or the Office of Science and Technology here have also been put to sleep.

We need to develop social technologies to assess our technologies. And in a way, when we were hearing earlier about the gap between our abilities to synthesize DNA and our ability to design, I was reminded of Martin Luther King's words that the gap — I think he talks about between the state of our wisdom and the state of our technical abilities, we have misguided men and guided missiles. The point being, we haven't put enough effort into developing the social technologies to assess and govern our technologies. And that is where I'd like to put money and effort and time. I think this commission could suggest that.

Amy Gutmann:
Christine.

Christine Grady:
First, I want to add my thanks to all three of you. Wonderful presentations. I actually want to direct my question to you, Dr. Snow.

You had mentioned — I understand the concern about things that are environmentally released — but you had mentioned the things like suicide genes and other techniques that might be built in o limit the possible damages that are created from these released substances. I am wondering if this particular area has a unique opportunity in that regard, to develop either suicide genes or chemical deactivators that make things destroy themselves after a while. And because it's synthetic, because we're synthesized and if we could build those things in as part of the trajectory early on in the research stage and as Nancy said, carefully assess them in the research stage, reassess them later, but, you know, have as a sort of bottom line always there needs to be something built in that will destroy this thing if it gets out of hand. What do you think about that?

Allison Snow:
I think that's a really interesting angle and there should be the potential for much more effective biological containment or confinement. Probably a company like Synthetic Genomics could handle that and could provide data on how accurate it is and how long lasting it is. There would always be some people who would say "Well, it could break down," but maybe it would be way better than anything that came before.

But another issue is that all companies aren't going to be that responsible. And there's going to be so many people in the world doing all kinds of experiments that it's still a concern I think, even if you have the ability to do it. But I do think that's a good point and I know there's research going on right now to try to develop those kinds of terminator-type technologies for new organisms.

Amy Gutmann:
Yes, Jim.

Jim Thomas:
Could I speak to that? Because our Organization, ETC, came up with the word "terminator technologies," and I think it's important before recommending suicide genes or terminator technologies, to look at the history of why they were originally developed.

Terminator technology was originally developed in order to enable large companies, like Monsanto, Delta Pine Lab, and so forth, to control seeds so they didn't get reproduced by small farmers, to exercise control of the monopoly in agriculture, particularly in the South and developing world, taking away the rights of small farmers, the very essential rights. And although now there's a discussion about whether we can use that technology for biosafety, it has to be remembered this technology is extremely interesting.

To large companies who want to maintain monopoly it also has dual use implications. If you can have switches, genetic switches, you can turn on and off traits from afar. And that could be used for a bioweapon. So it would be dangerous to endorse suicide technology on a biosafety basis without acknowledging that it's going to get used for monopoly and other uses. And there is an international moratorium on the use of genetic use restriction technologies through the conventional biological diversity and that shouldn't be overturned lightly. That should be respected.

Amy Gutmann:
Nita.

Nita Farahany:
Thank you. Mr. Thomas, I was particularly interested in your comment about resource limitations, and thinking about that. It's an aspect I hadn't thought about before. But like John, I want to kind of press you a little bit on what your bottom-line is because you call for a moratorium on the release of this, any sort of synthetic biology into the environment. And yet I'm not sure how you could ever get comfortable even post-moratorium, particularly if the terminator technologies are ones we shouldn't be endorsing, and if to professor Snow's point said if these technologies are ones that through future generations self-replication they may be overcome. I wonder if there is any way you could ever actually get comfortable even once the

moratorium is initiated, or are you really just calling for a ban on this technology entirely?

Then, Professor King, I wonder if you could speak to, you mentioned long-term surveillance and monitoring once we release the technology could be effective. But what if Professor Snow is right and if there's any sort of terminator technology built in, they are simply overcome by, you know, the process of replication. Is that really an effective strategy to do surveillance or long-term monitoring if there's no containment possible?

Jim Thomas:
I think I understand your question. We're asking for a moratorium, but are we really asking for a ban?

Nita Farahany:
Yes.

Jim Thomas:
It's true. There are bigger concerns based on the economy that would flow from this than the justice questions. But I think this points to questions about democracy and technology and if there was to be a way of truly governing our technologies so there was a democratic assent. And we don't have the social technology to do that. Then, you know, through that process, people in Kenya, people in the South, particularly who are going to be most affected, say actually maybe we need this technology, well, yeah, maybe that's the occasion.

Amy Gutmann:
Jim, could I just ask you very simply? We don't have a democratic way of assent to it. But neither do we have a democratic way of banning it.

Jim Thomas:
Yeah.

Amy Gutmann:
Doesn't that argument work both ways?

Jim Thomas:

I think there is a larger problem here about the lack of democratic control over technology and science. And, you know, whether it's synthetic biology or geo-engineering or nanotechnology, it's just one of a number.

Amy Gutmann:
But I think it's important that that argument both proves too much and too little.

Jim Thomas:
Yes.

Amy Gutmann:
There was another question, the same question to Nancy.

Nancy King:
Well, this was a question with respect to does long-term monitoring really matter if containment turns out to not be possible? Well, I think the reason I mentioned long-term monitoring really is that we haven't done it for any technology. And most of my experience is with gene transfer research, that long-term monitoring of the effects of gene transfer on research subjects and even viral shedding, which everybody was worried about at the beginning of gene transfer and got less worried about, hasn't really been followed. I mean there isn't the funding for it. It simply isn't being done.

Most gene transfer, although they do use suicide genes in gene transfer research as well, most gene transfer, you can't undo the effects. But we don't know what the long-term effects are. So even if containment weren't possible, it seems to me to make a lot of sense to start doing long-term monitoring so that we can simply see the effects, since after all, I mean the ecology is sort of a moving target anyway, even if we can't contain, if something needs to be done, we can't figure out what it might be unless we know what the effects are.

Amy Gutmann:
I'm going to see if there are any questions from the members of our public. We're going to move on to the next session without a break, so I'm going to take five minutes. Please come up to the mic and introduce yourself.

Owen Schaefer:
Hi. Owen Schaefer, NIH. I had a question for Jim Thomas. Sorry you get so many, very but interesting comments. It was about the examples which you gave of the two examples in particular that struck me. The Brazilian I guess sugar slave example and then the problem of farmers losing their competitive edge. But don't these seem like the problems of not only synthetic biology but a lot of the modern economy? Don't these problems seem in tension of each other?

In some way, the solution to one kind of causes the problem of the other. The sugar slave example, if we say, "okay, a solution to this can be we don't have production in these kinds areas, but then you have members of the farming community in Brazil which no longer are able to sell their sugar at the right prices. On the other hand, if you have the farmers and you want to say we're going to increase our purchase of food from all these farmers in third-world problem of human rights abuses in these areas. How do you — it seems it doesn't matter what you do, you're going to end up with human rights abuses in these situations. Seems like there isn't a solution. It's not synthetic biology. It's just the modern economy.

Jim Thomas:
Sugar production in Brazil is highly concentrated and it's very large companies. You're talking about a power structure where large companies are hiring migrant laborers at close to slave conditions.

When you're talking about east African Artemesinin farmers, you're talking about small farmers with a bit more of admittedly, still poor farmers. And yeah, you're right. What we are pointing to that there are real disparities in terms of the rights and livelihoods of people in the global South that's going to be affected and already affected by the global economy and going to continue to be affected by these changes in the global economy. I think my point is that, is synthetic biology going to improve the lives of people — the largest majority of people in the world? I don't think it is. And therefore, I would wonder if that's the direction we want to be going in our technological research.

Amy Gutmann:
Yes. Up to the mic, please. Thank you.

Susan Poland:

Hello. I'm Susan Poland. And I would like to speak about, from my experiences at the Jones Institute for Reproductive Science in Norfolk and my experience at the Kennedy Institute Center for Bioethics, Bioethics Library, comparing in-vitro fertilization technology to synthetic biology. The common issue to both is actually reproduction, whether you call it creation or cloning or booting up, it's still going to be reproduction. And there are two common concerns. One is control on growth and on cessation of growth. And the other one is implantation which this group has been speaking of mostly as containment. And the implantation or release has to do with context to the body or with the environment. I went to a CDC conference in 2002 in June right after the SARS epidemic and the Canadian delegation stood up and spoke about controlling and actually how the SARS epidemic came into Canada and then went through Canada and everyone stood up and gave them a standing ovation because we realized that could have been us. And they said the one thing that they did was a lost opportunity with the SARS epidemic and that was to educate the public about the difference between infectious genetic disease even though we had already gone through AIDS. This group and my question is actually for you, Dr. Gutmann and Dr. Wagner and maybe the whole group, based on all previous experiences. Who has the ethical obligation, who has the legal responsibility, to educate the public about science — and then, which public? Are we talking about a blue ribbon public already well versed in this area that knows to come to this meeting in the middle of July? Or is it the public the people reading their summer reading lists out there? It's more inclusive. Is this a passive obligation? Is this an active obligation? In the past, I've seen it be very passive. It's like, "No, the scientists have to go out and do it." And then, Is this a public obligation or a private obligation? To this end, you have an opportunity just like the people did with the SARS. Right now, you have six months, three meetings, school time starting in about another six weeks when my work ends at the Kennedy Institute, by the way. And in that time, you could put together a very short unit for all the biology teachers through all the high schools explaining to these kids how synthetic biology works, what the tools are. And they can go home and talk to their parents about it and start thinking about their science fair projects about ethical obligations or whatever. This is your window of opportunity. And my last comment has to do since I've written on bioethics commissions, councils, and committees, has to do with, the fact that there is an inherent conflict between the global nature of science and the national nature of regulation. And as an American advisory body, this group can make recommendations that work, such as the Nuremberg code or better yet the Helsinki accord, although I recognize that we're talking more than about basic science and engineering rather than medical science. You can set a model that can be adopted or adapted, depending on each country , that will be used by regulatory bodies worldwide. Thank you.

Amy Gutmann:
Thank you very much. You asked some questions there to Jim and me. And I will give you my very brief answer without the reasons behind it.

The responsibilities are widespread, including the responsibility of this body, to do our job as best we can to publicly educate after hearing both from experts in the field and people like you who have really legitimate concern about what's going on, number one.

Number two, you asked whether our responsibility was passive or active. It is definitely active. We have done our very best, even having a meeting early in July, despite the fact it's the summer to get the word out and really invite the public. And we will be meeting around the country. We are a body constituted by the President of the United States and, therefore, our first obligation is to do outreach to the American public. But these meetings are open to anybody who wishes to attend. So, second, active, not passive.

And third, it is a public and a private responsibility. I think it would be a mistake to say this was just the public possibility, although it is first and foremost a responsibility of the public. But private bodies also have ethical responsibilities here. Thank you very much for that. And I'm going to ask Jim to add something to that since you addressed it, to both Jim and myself. Then we will move on to the next session.

Jim Wagner:
More broadly, I would agree with you that it's probably within the

scope of the report of this group to make some recommendations about education and the dissemination of information. Science literacy we know in our country is not even what it used to be. When you ask who is involved in that, well, as Amy has said, it's a broad responsibility. Yes, educational institutions can be involved. I think it's fascinating to look even at the fourth estate, to look at journalism and how journalism has changed its mission from the time where we had so much science education through journalism during the space race, for example. And that is gone now. So much of that is gone. So perhaps your contribution to our deliberations today is to ensure that somewhere in our report we make recommendations about public education. Thank you very much for that.

Amy Gutmann:
And I want to thank, on behalf of the Commission, our three wonderful presenters for lucid, informative, and provocative information and recommendations.

Thank you all very, very much.

[AUDIENCE APPLAUSE]